Expanding Access to Treatment for Opioid Use Disorder: Provider Perspectives on Reducing Barriers to Evidence-Based Care

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Medications for Treatment of Opioid Use Disorder Issue Background Paper

Introduction

The United States is currently experiencing a crisis of opioid-related misuse, opioid use disorder (OUD), and overdose. Millions of Americans suffer from OUD, commonly referred to as opioid addiction, which can involve prescription opioid analgesics, as well as illegal opioids such as heroin or illicitly manufactured fentanyl (IMF). According to the National Institute on Drug Abuse (NIDA), addiction is a chronic, relapsing disease of the brain, with cognitive, behavioral, and physiological effects, and is characterized by continued drug use despite harmful consequences. OUD is treatable, although continuing care needed to achieve the goal of remission and lasting recovery.

Although there is no “one-size-fits-all” approach to OUD treatment, there is strong evidence that the use of FDA-approved medications as a component of OUD treatment can help individuals with addiction achieve lasting recovery. The use of medications in combination with psychosocial behavioral therapies is often referred to as “medication-assisted treatment (MAT).” Supporting development, access, and adoption of medications for treatment of OUD is a key priority of the U.S. Food and Drug Administration (FDA). However, substantial challenges remain in patient access and provider utilization of effective therapies. According to survey data from the 2016 National Survey on Drug Use and Health (NSDUH), only 21 percent of persons with an OUD received treatment at a specialty facility. Despite the significant potential for treatment to reduce opioid-related morbidity and mortality for millions of Americans suffering from OUD, significant legal, regulatory, and practical challenges prevent many people from accessing to quality, evidence-based treatment.

Understanding Opioid Use Disorder

In the past several decades, scientific advances have led to breakthroughs in understanding the complex genetic, biological, behavioral, and social factors that contribute to substance use disorders, including OUD. Only a small percentage of people exposed to opioids will develop OUD, which is marked by structural and functional changes within the brain’s reward system. While individual susceptibility to addiction is highly variable and dependent on a variety of genetic, individual, and environmental factors, known risk factors include adolescence, history of substance use disorders, depression, long-term opioid usage, and higher daily opioid dosages. According to the most recent Diagnostic and Statistical

*Some within the provider community believe that the term “Medication-Assisted Treatment” contributes to stigmatization of these medications and perpetuates a belief in the ancillary role in treatment. Therefore, there has been a shift in preference to refer to the use of medications in OUD treatment as simply “treatment” or pharmacotherapy consistent with other chronic disease management. Throughout this document, references to “medications for treatment of OUD” will denote evidence-based treatment approaches that utilize FDA-approved medications in combination with comprehensive treatment services. A list of other key terms can be found in Appendix A.
Manual of Mental Disorders (DSM-5), OUD is characterized by a “problematic pattern of opioid use leading to clinically significant impairment or distress,” with symptoms that include excessive craving, persistent desire to cut down use, and continued use despite harm. Physical and behavioral changes for persons with OUD can persist long after physical dependence or exposure to opioids is eliminated. Patients receiving detoxification alone without linkage to pharmacotherapies or additional rehabilitative services are less likely to abstain from future opioid use and are at additional risk of overdose. Yet many people receiving detoxification or withdrawal management services for OUD do not enter treatment, and many people suffering from OUD fail to receive any sort of intervention. Addressing this gap requires long-term chronic care strategies that can help reduce symptoms of OUD, improve health and social function, avoid relapse, and manage and sustain recovery.

Evidence-Based Treatment Approaches for OUD Treatment throughout the Patient Care Continuum

According to the Substance Abuse and Mental Health Services Administration’s (SAMHSA) most recent Treatment Improvement Protocol 63 (TIP 63), the goal of treatment for OUD is “remission of the disorder leading to lasting recovery.” Although some patients may achieve recovery without the use of medications, ensuring access to FDA-approved medications is a key component to a comprehensive, person-centered disease management approach that includes access to mental health services, addiction counseling, and recovery support services. Patients may also require differing levels of care throughout the patient care continuum depending on the severity of their condition as well as other personal and environmental factors. Care settings may range from acute and intensive inpatient services, residential inpatient treatment, outpatient treatment and counseling, and long-term recovery support. Patients should continue to have access to medications for treatment of OUD as they transition through appropriate levels of care.

There is strong evidence supporting both the efficacy and cost-effectiveness of the use of medications for treatment of OUD. Studies have shown that using medications for treatment of OUD is more effective than treatment without medication, resulting in a reduction in opioid-related overdose, lower illicit drug use, and reductions in infectious disease rates and criminal activity. Subsequent studies have shown treatment with methadone and buprenorphine to be more cost effective than treatment without the use of medications, and that treatment with medications can lead to lower healthcare usage and costs.

Today, there are three medications approved by the FDA for long-term treatment of OUD: methadone, buprenorphine, and naltrexone. While all three have demonstrated efficacy for the treatment of OUD, each medication has different mechanisms, modes of administration, risks and benefits, regulatory restrictions, treatment settings, side effects, and relative risks of misuse and diversion. As such, the appropriate treatment may vary according to patient needs and considerations. A brief description of approved medications are as follows:

- **Methadone** is a full mu-opioid receptor agonist medication used in medically-supervised withdrawal and maintenance therapy. It has been in use over the past 40 years to help suppress opioid withdrawal symptoms and cravings, and has been shown to improve treatment retention rates and reduce illicit drug use over treatments without medication. Because methadone is a Drug Enforcement Administration (DEA) Schedule II controlled substance, its distribution is limited to federally-certified opioid treatment programs (OTPs). Patients undergoing methadone maintenance treatment receive daily doses in a medically-supervised setting.
- **Buprenorphine** is a mu-opioid receptor partial agonist that is used in OUD patients with mild to moderate opioid withdrawal symptoms who display a physiological dependence on opioids. Similar to methadone, buprenorphine has the ability to reduce opioid withdrawal symptoms, but has a “ceiling effect” that limits potential euphoria and respiratory depression compared to full opioid agonists. Many buprenorphine formulations include naloxone, a short-acting opioid agonist that blocks the effects of opioids, as a safeguard against misuse. It is available in transmucosal, implantable, and long-acting injectable forms. Under the Drug Addiction Treatment Act of 2000 (DATA 2000), buprenorphine can be prescribed by healthcare providers that undergo specialty training or at OTPs. Because buprenorphine can be delivered in a variety of healthcare settings (including primary care) and may not need to be taken daily, buprenorphine can provide the added benefit of flexibility and access for patients for whom methadone is not convenient.

- **Naltrexone** is an opioid antagonist that is used in OUD and alcohol use disorder. Naltrexone causes no opioid-like effects, blocks the euphoria associated with opioids, and reduces opioid cravings. In extended-release injectable forms, naltrexone has been shown to reduce opioid use and retain patients in treatment more effectively than treatments carried out without medication. Any physician may prescribe naltrexone, but patients must achieve medical withdrawal from opioids (from 7 to 14 days, depending on the opioid) before undergoing treatment, which can present a substantial barrier to treatment induction.

According to SAMHSA, medications should be used in OUD treatment as “maintenance treatment” for as long as the patient continues to receive benefits from the medication. By minimizing cravings and withdrawal symptoms, patients are able to cease or significantly decrease opioid use, leading to reductions in overdose risk. Furthermore, patients stabilized on medications show better retention in treatment, leading to the ability to make changes that support long lasting recovery.

**Addressing the “Treatment Gap:” Barriers to Access to Medications for Treatment of OUD**

Despite the strong evidence for the effectiveness of medications for treatment of OUD, they remain significantly underutilized. According to SAMHSA’S National Survey of Treatment Centers, in 2016, 27 percent of all treatment facilities (outpatient, residential, hospital inpatient, or OTP) provided buprenorphine services while 21 percent of facilities provided extended-release naltrexone treatment. One additional study estimated that medications for OUD treatment are routinely used in less than 50 percent of private sector settings. Of those settings offering medications for treatment of OUD, only 34.4 percent of patients actually received them as part of their treatment plan. In one analysis, 96 percent of states reported opioid misuse or dependence rates significantly higher than buprenorphine administration capacity rates. This shortfall may be particularly pronounced in rural geographic areas, where as many as 30 million persons live in counties without access to buprenorphine treatment.

Despite these challenges, recent data released by SAMHSA indicates that treatment capacity is increasing in response to the severity of the opioid crisis. The number of OTPs increased 39 percent between 2003 and 2016, with these facilities demonstrating marked increases in the number of patients receiving buprenorphine. DATA 2000 permits physicians meeting certain requirements to obtain a waiver to prescribe buprenorphine in treatment settings other than OTPs (i.e., office-based settings). Recent changes have also sought to expand access to Office-Based Opioid Treatment (OBOT) by allowing physician’s assistants and nurse practitioners to prescribe buprenorphine after undergoing 24 hours of training (as allowed by individual states’ scope of practice regulations) and concurrently increasing the
number of patients able to be prescribed buprenorphine by a waivered practitioner from 100 to 275 patients.\textsuperscript{36}

Even with these advances, significant legal, regulatory, policy, and practical barriers still inhibit provider utilization—and ultimately patient access—to these effective therapies. Due to the potential for misuse, diversion, and overdose, opioid agonist therapies are tightly regulated in OTP settings where methadone distribution must be medically supervised. In one survey of addiction treatment programs choosing not to provide medications, nearly 80 percent of programs reported that a lack of medical personnel prevented them from being able to comply with the state regulations needed to offer medications for treatment of OUD.\textsuperscript{37} Additional surveys of providers found that providers cited a lack of belief in agonist treatment, insufficient time for additional patients, and belief that reimbursement rates are insufficient as barriers to utilization of OBOT.\textsuperscript{38} Nationally, only 16 percent of primary care physicians have undergone the required DATA-waiver training, demonstrating that treatment could be significantly expanded with greater waiver participation.\textsuperscript{39} However, evidence suggests that most waivered prescribers are currently prescribing buprenorphine to patients at rates well below their allowable limits.\textsuperscript{40}

Payment challenges relating to coverage and reimbursement also rank highly on provider-reported barriers to utilization of medications for treatment of OUD. Despite requirements to provide behavioral health coverage at parity with physical health, an analysis by the American Society of Addiction Medicine (ASAM) found that a number of policies contributing to a lack of access to medications were common across state Medicaid programs. These policies include lack of coverage of FDA-approved medications, arbitrary limits on recommended dosage or refills, lifetime limits on medications, burdensome and time-consuming prior authorization processes, “fail first” or “step therapy” criteria, requirements for extensive documentation, and a lack of coverage for required counseling.\textsuperscript{41} Many of these policies can constitute barriers in the private insurance market as well. For patients with either public or private insurance, the lack of treatment capacity or in-network providers remains a significant challenge to accessing high-quality care.

Along with the existence of these systemic policy barriers, there is perhaps no greater challenge to expanding the use of medications for treatment of OUD than the prevalence of negative attitudes and stigma. The belief that medications are replacing “one addiction for another” is persistent and contributes to a lack of uptake of medications.\textsuperscript{42} Despite ample evidence on the effectiveness of medications for treatment of OUD, data indicates that negative opinions by healthcare providers persist.\textsuperscript{43} In one survey of 648 primary care providers, physicians reported a lack of adequate training on addiction, time and resource constraints, skepticism about treatment effectiveness, and a general discomfort associated with discussing substance abuse as concerns for treating patients with substance use disorders.\textsuperscript{44} Finally, patients themselves—many of whom have a variety of complex medical, psychiatric, and social needs—also face considerable barriers related to stigma and navigation of a disjointed treatment system. Oftentimes, patients are also concerned with practical or financial aspects associated with seeking care, including payment, job security, child care, or transportation.
Conclusion

Opioid-related misuse, addiction, and overdose continues to be a public health challenge in the United States. While there is no single approach to OUD treatment, increasing access to FDA-approved medications in combination with psychosocial behavioral therapies has the potential to help individuals with addiction achieve lasting recovery. In order to overcome the legal, regulatory, and practical barriers that have prevented further adoption and access to these important medications, the Duke-Margolis Center for Health Policy, under cooperative agreement with the FDA, is holding this public workshop to generate an active discussion with provider communities and clinical experts on the armamentarium of therapies to treat OUD, understand barriers to appropriate use of these medications, and discuss opportunities to further reduce stigma and expand access to effective OUD pharmacotherapies as part of an evidence-based approach to treatment of OUD.
Key Terms (as Defined by SAMHSA TIP 63)

**Addiction**: As defined by the American Society of Addiction Medicine, “a primary, chronic disease of brain reward, motivation, memory, and related circuitry.” It is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), does not use the term for diagnostic purposes, but it commonly describes the more severe forms of OUD.

**Medically supervised withdrawal** (formerly called detoxification): Using an opioid agonist (or an alpha-2 adrenergic agonist if an opioid agonist is not available) in tapering doses or other medications to help a patient discontinue illicit or prescription opioids.

**Medical management**: Process whereby healthcare professionals provide medication, basic brief supportive counseling, monitoring of drug use and medication adherence, and referrals, when necessary, to addiction counseling and other services to address the patient’s medical, mental health, comorbid addiction, and psychosocial needs.

**Office-based opioid treatment (OBOT)**: Providing medication for OUD in outpatient settings other than certified opioid treatment programs (OTPs).

**Opioid misuse**: The use of prescription opioids in any way other than as directed by a prescriber; the use of any opioid in a manner, situation, amount, or frequency that can cause harm to self or others.

**Opioid receptor agonist**: A substance that has an affinity for and stimulates physiological activity at cell receptors in the central nervous system that are normally stimulated by opioids. **Mu-opioid receptor full agonists** (e.g., methadone) bind to the mu-opioid receptor and produce actions similar to those produced by the endogenous opioid beta-endorphin. Increasing the dose increases the effect. **Mu-opioid receptor partial agonists** (e.g., buprenorphine) bind to the mu-opioid receptor. Unlike with full agonists, increasing their dose may not produce additional effects once they have reached their maximal effect. At low doses, partial agonists may produce effects similar to those of full agonists.

**Opioid receptor antagonist**: A substance that has an affinity for opioid receptors in the central nervous system without producing the physiological effects of opioid agonists. Mu-opioid receptor antagonists (e.g., naltrexone) can block the effects of exogenously administered opioids.

**Opioids**: All natural, synthetic, and semisynthetic substances that have effects similar to morphine. They can be used as medications having such effects (e.g., methadone, buprenorphine, oxycodone).

**Opioid treatment program (OTP)**: An accredited treatment program with SAMHSA certification and Drug Enforcement Administration registration to administer and dispense opioid agonist medications that are approved by FDA to treat opioid addiction. Currently, these include methadone and buprenorphine products. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to these regulations. OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner through a formal agreement.

**Opioid use disorder (OUD)**: Per DSM-5, a disorder characterized by loss of control of opioid use, risky opioid use, impaired social functioning, tolerance, and withdrawal. Tolerance and withdrawal do not count toward the diagnosis in people experiencing these symptoms when using opioids under appropriate medical supervision. OUD
covers a range of severity and replaces what DSM-IV termed “opioid abuse” and “opioid dependence.” An OUD diagnosis is applicable to a person who uses opioids and experiences at least 2 of the 11 symptoms in a 12-month period.

**Psychosocial treatment:** Interventions that seek to enhance patient’s social and mental functioning, including addiction counseling, contingency management, and mental health services.

**Recovery:** A process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. Even individuals with severe and chronic SUDs can, with help, overcome their SUDs and regain health and social function. Although abstinence from all substance misuse is a cardinal feature of a recovery lifestyle, it is not the only healthy, prosocial feature. Patients taking FDA-approved medication to treat OUD can be considered in recovery.

**Relapse:** A process in which a person with OUD who has been in remission experiences a return of symptoms or loss of remission. A relapse is different from a return to opioid use in that it involves more than a single incident of use. Relapses occur over a period of time and can be interrupted. Relapse need not be long lasting. The TIP uses relapse to describe relapse prevention, a common treatment modality.

**Remission:** A medical term meaning a disappearance of signs and symptoms of the disease. DSM-5 defines remission as present in people who previously met OUD criteria but no longer meet any OUD criteria (with the possible exception of craving). Remission is an essential element of recovery.


13 Volkow et al.


18 Ibid.

19 Ibid.


31 Ibid.